



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,760	03/31/2004	Joel E. Bernstein	41959-102739	5267
23644 7590 08/05/2010 BARNES & THORNBURG LLP P.O. BOX 2786 CHICAGO, IL 60690-2786				
EXAMINER				
KWON, BRIAN YONG S				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
08/05/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10813760	3/31/2004	BERNSTEIN, JOEL E.	41959-102739

EXAMINER

Brian-Yong S. Kwon

ART UNIT	PAPER
1614	20100731

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

. Receipt is acknowledged of Appellant's Reply Brief filed September May 27, 2010, which papers have been placed for record in the file. No further commentary is needed.

.Appellant's argument in the response takes the similar position as the previous argument that Table 5 of Kroger'99 teaches away from the elements of Appellant's claimed invention. Appellant argues that Table 5 of Kroger'99 shows that administering 50 m/kg of nicotinamide in combination with acetaminophen and methotrexate demonstrated increased liver toxicity compared to acetaminophen and methotrexate administered alone; that administering higher doses of nicotinamide in combination with acetaminophen and methotrexate was non-hepatoprotective compared to acetaminophen and methotrexate administered alone; and that a skilled artisan would be strongly discouraged by Kroger'99 from using nicotinamide in a drug-induced hepatotoxicity model including acetaminophen due to the ineffective and counterproductive effects of nicotinamide in mitigating hepatotoxicity.

Appellant's argument is not found persuasive. Again, the examiner likes to clarify that appellant made an election of Group I invention (a composition claims) along with acetaminophen as the single disclosed species from generic "a hepatic compound". Accordingly, appellant received an action on the merits for the originally elected invention (Response filed 02/28/2007). Contrary to the merits of the case, Kroger'99 reference mainly relates to the activity of nicotinamide and methionine in reducing the liver toxic effect of methotrexate. It is evident from the reading Table 3 of Kroger'99 (as well as line 3 of the abstract) that acetaminophen at 50 mg/kg utilized in the study is not known to cause hepatotoxicity. Although the examiner recognizes appellant's reliance of Table 5 of Kroger'99 in supporting "teaches away" from the instant invention, the examiner cannot find any evidence from Kroger'99 that methionine and/or nicotinamide actually increase the liver toxicity of acetaminophen alone, which is contradictory to Kroger'97 study. Even assuming arguing that Kroger'99 is relevant to the merits of the case, Table 5 discloses that with increasing NA doses, there is a reduction in GOT and GPT activities. Thus, reading the entire context of Kroger'99 reference (considering the totality of the prior art), one having ordinary skill in the art would have perceived that the simultaneous administration of either nicotinamide or methionine or both together would be useful in reducing the liver toxic effect of methotrexate, more broadly other drugs at doses known to be hepatotoxic, e.g., acetaminophen (see last ten lines in column 2 of page 205, under "Discussion" of Kroger'99).

.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR)

system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614